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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,777	10/07/2003	Robert R. Gonnelli	BVTP-P01-034	6708

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EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,777

Applicant(s)

GONNELLI ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/07/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16 is/are rejected.
- 7) ☐ Claim(s) 4, 14 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/28/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/22/2005</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a transdermal delivery device and a transdermal patch, classified in class 604, subclass 46.
- II. Claim 17-20, drawn to a method of introducing a substance into the skin, classified in class 604, subclass 290.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case substances can be introduced into the skin by using other products such as micorabraders.

During a telephone conversation with Edward Kelly on June 7, 2005 a provisional election was made without traverse to prosecute the invention of a transdermal delivery device, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: The term "accurate" on page 7, line 20 and on page 8, line 16 should be changed to "arcuate". Add the term "a" in between "including" and "drug" on page 16, line 14. The term "drug"

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on page 21, line 19 should be changed to the plural form. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the flange and the flow controller must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 4, 14 and 16 are objected to because of the following informalities: In regards to claim 4, the term "introduce" should be changed to "introduced". In regards to claim 14, delete the term "to" between "coupling" and "the". In regards to claim 16, replace the term "as" with "and". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 13 discloses a spring assembly to be included in the device as recited in claim 12, which depends from claim 1. Claim 1 discloses a pin and references the embodiment illustrated in Figure 5a and 5b. There is no disclosure of a spring in this embodiment in the drawing or specification. The examiner cannot determine how the springs are used in this embodiment of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Safabash et al. (6,293,925).

Safabash et al. clearly discloses a delivery device that includes all of the limitations as recited in claim 1. See Figure 16 and the respective portions of the specification. Safabash et al. discloses a device with a microneedle (26) that has an interior channel for pin (12) to slidably move within the channel. The device is anchored to the skin by adhesive patch (24).

In regards to claim 2, Safabash et al. discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the tip of the pin (12) has an arcuate distal end for piercing biological tissue.

In regards to claim 3, Safabash et al. discloses a delivery device that includes all of the limitations as recited in claim 1 wherein a handle (18) is provided for sliding the pin in and out of the channel.

In regards to claim 14, Safabash et al. discloses a delivery device that includes all of the limitations as recited in claim 1 wherein a flange (20) is attached to infusion tubing (22) that connects to another medical device such as a pump.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. (4,324,236).

Gordon et al. discloses a delivery device that includes all of the limitations recited in claims 1-3. See Figure 7 and the respective portions of the specification. Gordon et al. discloses a device comprising a microneedle (40), an arcuate pin (42) that is slidable within the microneedle (40), and an adhesive patch (38) that binds the device to the skin of a patient.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-7, 11-12, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Ackley (09/747,768).

Ackley discloses a delivery device that includes all of the limitations as recited in claim 1. See Figure 1 and the respective portions of the specification. Ackley discloses a device that includes a hollow microneedle (22) with two other microneedles (also numbered 22) disposed within the lumen of the first microneedle (22). These two microneedles can be seen as pins and would perform the same function as the pin of the applicant's invention. The different layers (18) of the device are held together by an adhesive patch, which is strong enough to bind to biological tissue.

In regards to claim 2, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the pins have arcuate distal ends that are capable of piercing biological fluid.

In regards to claims 4 and 5, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the device includes a reservoir (26) with multiple chambers that can store and dispense multiple therapeutics at the same time.

In regards to claims 6 and 7, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein a pump with a flow controller can be used to pump fluid through the device and control the fluid flow through the microneedles. See page 4, paragraph (0051).

In regards to claim 11, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the microneedle (12) comprises an array of microneedles formed on a substrate (24).

In regards to claim 12, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the pins (defined above) comprise an array of pins.

In regards to claim 14, Ackley discloses a delivery device that includes all of the limitations as recited in claim 1 wherein the device comprises a flange (not shown) to connect to an external device such as a pump.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (5,820,570) in view of Gertsek et al. (6,656,147).

Erickson et al. discloses a transdermal fluid collector that includes all of the limitations as recited in claims 1, 4, and 15. See Figure 2 and the respective portions of the specification. Erickson et al. discloses a device that a microneedle (42), a pin (12) that slidably fits within the lumen of microneedle (42), a reservoir (76) for storing fluid, and a pump (70) for drawing fluid into the reservoir. Erickson et al. does not teach to add an adhesive patch to the device to allow it to adhere to the skin of a patient.

Gertsek et al. discloses a transdermal delivery device that delivers fluids to the skin of a patient. Gertsek et al. teaches to use an adhesive patch (28) on the base of the device to attach the apparatus to the skin of a patient. See column 2, lines 60-61.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an adhesive patch, as disclosed by Gertsek et al., to the transdermal fluid collector, as disclosed by Erickson et al., to make a transdermal fluid collector that can adhere to skin of a patient without assistance from the hands of a technician.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunmire et al. (3,289,675) in view of Gertsek et al. (6,656,147).

Dunmire et al. discloses a delivery device that includes all of the limitations as recited in claims 1-4 and 8. See Figure 1 and the respective portions of the

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specification. Dunmire et al. discloses a delivery device that has a microneedle (28) that has a distal end and an interior lumen. A pin (25) is slidably disposed within the lumen with a handle (26) attached to the pin for moving the pin in and out of the lumen. The pin (25) has an arcuate distal end for piercing biological tissue. The device also includes a reservoir (20) for storing fluid. Dunmire et al. also discloses a plug (36) at the distal end of the channel, which can prevent tissue from entering the lumen of the microneedle (28). Dunmire et al. does not disclose to add an adhesive patch to the device to enable it to adhere to the skin of a patient.

Gertsek et al. discloses a transdermal delivery device that delivers fluids to the skin of a patient. Gertsek et al. teaches to use an adhesive patch (28) on the base of the device to attach the apparatus to the skin of a patient. See column 2, lines 60-61.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an adhesive patch, as disclosed by Gertsek et al., to the delivery device, as disclosed by Dunmire et al., to make a delivery device that can adhere to the skin of a patient without assistance from the hands of a technician.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash et al. (6,293,925) in view of Cable et al. (4,685,903).

Safabash et al. discloses a delivery device that includes all of the limitations as recited in claim 1. Safabash does not disclose a pump that controls the flow rate of fluid through the delivery device. Cable et al. discloses an insulin pump that can control the rate of fluid flow through a delivery device. Safabash teaches to use the pump of Cable

et al. with the delivery device to deliver insulin to a patient in a controlled manner. See col. 8, lines 35-40 of Safabash et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the pump, as disclosed by Cable et al., with the delivery device, as disclosed by Safabash et al., to make a device that can pump fluid into or beneath the skin in a controlled manner.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leong et al. (6,837,988) in view of Gertsek et al. (6,656,147).

Leong et al. discloses a transdermal patch that includes all of the limitations as recited in claim 16. See Figure 1A and the respective portions of the specification. Leong et al. discloses a transdermal patch (10) with hollow microneedles (12) and a plug (22) that is disposed within the lumen of microneedles (12). Leong et al. does not teach to add an adhesive patch to the device to allow it to adhere to the skin of a patient.

Gertsek et al. discloses a transdermal delivery device that delivers fluids to the skin of a patient. Gertsek et al. teaches to use an adhesive patch (28) on the base of the device to attach the apparatus to the skin of a patient. See column 2, lines 60-61.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an adhesive patch, as disclosed by Gertsek et al., to the transdermal patch, as disclosed by Leong et al., to make a transdermal patch that can adhere to skin of a patient without assistance from the hands of a technician.

Allowable Subject Matter

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Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 2,522,309 to Frank
US Patent 6,183,434 to Eppstein
US Patent 6,256,533 to Yuzhakov et al.
US Patent 6,334,856 to Allen et al.
US Patent 6,503,231 to Prausnitz et al.
US Patent 6,537,242 to Palmer
US Patent 6,591,124 to Sherman et al.
US Patent 6,603,998 to King et al.
US Patent 6,713,291 to King et al.
US Patent 6,743,211 to Prausnitz et al.
US Patent 5,569,272 to Reed et al.
US Patent 5,697,901 to Eriksson
US Patent 5,931,794 to Pitesky
US Patent 6,083,196 to Trautman et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS

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A handwritten signature in black ink, appearing to read 'N. Lucchesi', with a stylized, flowing script.

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700